JUL - 6 2004

K040459

510(k) Summary of Safety and Effectiveness

Triage® Profiler S.O.B. Calibration Verification Controls / Triage® Profiler S.O.B. Controls

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: (To be determined)

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	11030 Roselle Street San Diego, CA 92121
Telephone:	(858) 455-4808
Fax:	(858) 535-8350
Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	2/20/05

B. Device Names

1. Trade Name

   Triage® Profiler S.O.B. Calibration Verification Controls / Triage® Profiler S.O.B. Controls

2. Common / Usual Name

   Not Applicable

3. Classification Name

   Quality Control Material (Assayed and Unassayed)
   21 CFR 862:1660
   Class I
   Product Code: JJY

C. Predicate Devices

Triage Cardio ProfilER Calibration Verification Controls (K030088)
Triage Cardio ProfilER Controls (K030089)

D. Device Description and Intended Use

The Triage® Profiler S.O.B. (Shortness of Breath) Calibration Verification Controls are to be used with the Triage® Profiler S.O.B. Panel and Triage® Meter Plus to verify the calibration of the Triage® Profiler S.O.B. Panel throughout the measurable range.

The Triage® Profiler S.O.B. (Shortness of Breath) Controls are to be used with the Triage® Profiler S.O.B. Panel and Triage® Meter Plus to assist the laboratory in monitoring test performance.

E. Summary of Comparison Data

The table below provides a comparison of the technical principles between the Triage® Profiler S.O.B. Calibration Verification Controls / Triage® Profiler S.O.B. Controls and the predicate devices.

Characteristic	**Triage® Profiler S.O.B. Controls / Calibration Verification Controls**	**Triage® Cardio Profiler Controls / Calibration Verification Controls (K030088, K030089)**
Intended Use	Assayed control for monitoring test performance	Assayed control for monitoring test performance
Matrix	EDTA plasma	EDTA plasma
Form	Liquid	Liquid
Analytes	CK-MB, Troponin I, Myoglobin, BNP, D-dimer	CK-MB, Troponin I, Myoglobin, BNP
Storage	-20 °C or colder	-20 °C or colder

F. Conclusion

The information provided in the premarket notification demonstrates that the Triage® Profiler S.O.B. Calibration Verification Controls / Triage® Profiler S.O.B. Controls are substantially equivalent to previously approved predicate devices. The information provided assures that the Triage® Profiler S.O.B. Calibration Verification Controls / Triage® Profiler S.O.B. Controls are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 6 2004

Jeffrey R. Dahlen, Ph.D
Principal Scientist, Clinical & Regulatory Affairs
Biosite Inc.
11030 Roselle Street
San Diego, CA 92121

Re: k040459
Trade/Device Name: Triage® Profiler S.O.B. (Shortness of Breath) Calibration Verification Controls
Triage® Profiler S.O.B. (Shortness of Breath) Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assay and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: June 28, 2004
Received: June 29, 2004

Dear Dr. Dahlen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040459

Device Name: Triage® Profiler S.O.B. (Shortness of Breath) Calibration Verification Controls

Triage® Profiler S.O.B. (Shortness of Breath) Controls

Indications For Use:

The Triage® Profiler S.O.B. (Shortness of Breath) Calibration Verification Controls are to be used with the Triage® Profiler S.O.B. Panel and Triage® Meter Plus to verify the calibration of the Triage® Profiler S.O.B. Panel throughout the measurable range.

The Triage® Profiler S.O.B. (Shortness of Breath) Controls are to be used with the Triage® Profiler S.O.B. Panel and Triage® Meter Plus to assist the laboratory in monitoring test performance.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040459